



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District *g 4426d*

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

November 13, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 06-04

Donald L. Pope
President
Brookhurst Mill
3315 Van Buren Blvd.
Riverside, CA 92503

Dear Mr. Pope:

An inspection of your licensed (No. 500-469) medicated feed mill, Brookhurst Mill, located at 3315 Van Buren Blvd., Riverside, California, conducted by Mr. John A. Gonzalez, a Food and Drug Administration (FDA) Investigator, from May 25 through June 2, 2003, disclosed significant deviations from the current good manufacturing practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR Part 225)]. Such deviations cause feeds manufactured at your facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 351(a)(2)(B)).

Section 501(a)(2)(B) of the Act (21 U.S.C. § 351(a)(2)(B)) states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP, to assure that such drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Our Investigator documented that the methods used in and the controls used for the manufacture of your medicated feeds are not in conformity with CGMP. These deviations from the regulations were reported to you in the Form FDA

483-Inspectional Observations (FDA-483), which was issued at the conclusion of the inspection on June 2, 2003 and included, but are not limited to, the following:

- Failure to test on a periodic basis feeds manufactured using a Category II Type A medicated article. Specifically, you did not conduct the required number of assays of all medicated feeds containing [REDACTED] (carbadox) during the calendar year 2002. [21 CFR § 225.58 (b)(1)]
- Failure to fully investigate the cause(s) of out-of-specification assays. Specifically, you did not investigate Pig Starter 20% Mash made on May 15, 2002, which was found to contain 162% of the labeled claim, or Pig Starter 20% Mash made on December 17, 2002, which was found to contain 38% of the labeled claim. [21 CFR § 225.58(d)]
- Failure to review batch production records on a daily basis. Specifically, your firm is not reviewing daily production records to assure that all feeds were manufactured correctly. [21 CFR § 225.102(b)(4)]
- Failure to maintain complete batch history records. Specifically, your firm does not maintain a history of changes in formulas or labeling. Copies of formulas and/or labels are not maintained for the minimum of one year past the last date of production. [21 CFR § 225.102(b)(1)]

We have received and reviewed your written responses to the June 2, 2003, FDA-483. Your responses indicate that you have taken corrective actions to address our concerns about the segregation of feeds containing prohibited materials and ruminant feeds. However, it does not address our concerns related to the lack of required assays, the lack of investigation into out-of-specification assay results, the lack of review of batch records, or the failure to maintain the history of obsolete formulas and labels.

We remain very concerned about your firm's continued lack of required assays and lack of adequate investigation of out-of-specification results. While your firm has previously investigated out-of-specification assay results, the extent of those investigations appears insufficient to identify the root cause. Out-of-specification assays may be the result of any number of circumstances. It is critical that you evaluate all possible causes and determine as objectively as possible the likely cause for the unexpected or out-of-specification result. Possible causes to consider include, but are not limited to: age and storage conditions of the medication, mixing time, age and quality of the equipment used, scale accuracy, sampling technique, physical characteristics of the equipment and commodities, and human error. Each contributing factor should be considered when corrective action is implemented. There are numerous resources available for additional guidance in this area. These include university outreach services, industry associations, private consultants, and government agencies.

In addition, a review of our records indicates that the last renewal of your Drug Establishment Registration with the FDA was done on January 10, 2000. Since that date, you have failed to renew your registration information annually with the FDA, as required by 21 CFR §§ 207.20 and 207.21. By signing your Medicated Feed Mill License Application (No. 500-469) on May 27, 1997, you committed to comply with this requirement.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your milling facility. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute comply with the law. Several of the violations noted during the most recent inspection are similar to those cited during previous inspections.

You should take prompt action to correct and prevent recurrence of these violations. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License No. 500-469 under section 512(m)(4)(B)(ii) of the Act (21 U.S.C. § 360b) and 21 CFR § 515.22(c)(2).

Based on the results of the May 25 through June 2, 2003 inspection, evaluated together with the evidence before FDA when your Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to ensure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above-cited deficiencies.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the specific actions taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. Please include copies of any available documentation showing that corrections have been made. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. We will verify that corrections have been properly implemented during our next inspection of your feed mill.

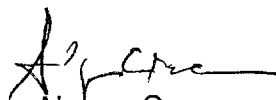
If you have any questions regarding this letter prior to your written response, you may contact Barbara J. Rincon, Compliance Officer at (949) 608-4439.

Letter to Mr. Pope
November 13, 2003
Page 4

Please direct your written response to the attention of:

Acting Director, Compliance Branch
United States Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,

A handwritten signature in black ink, appearing to read 'Aloha Cruse', with a stylized flourish at the end.

Aloha Cruse
District Director